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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0333; FRL-9970-88]

#### Chlorfenapyr; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile, in or on tea, dried. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0333, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202)

566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Goodis, P.E., Director, Registration Division (750P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfrNotices@epa.gov](mailto:RDfrNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0333 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0333, by one of the following methods:

- *Federal eRulemaking Portal: <http://www.regulations.gov>.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of July 20, 2016 (81 FR 47150) (FRL-9948-45), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8473) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.513 be amended by establishing tolerances for residues of the insecticide chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile, in or on tea, dried at 70 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. This tolerance was requested to cover residues of chlorfenapyr in or on tea resulting from uses of this pesticide on tea outside the United States. There is no current U.S. registration for use of chlorfenapyr on tea. In addition, there were no substantive comments received in response to the notice of filing.

## **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for

which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for chlorfenapyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with chlorfenapyr follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Chlorfenapyr has moderate acute toxicity via the oral route of exposure and low acute toxicity via the dermal and inhalation routes of exposure. It is a mild eye irritant, but it is not a dermal irritant or sensitizer. Chlorfenapyr targets the central nervous system (CNS), inducing neurohistological changes (spongiform myelinopathy of the brain and spinal cord and vacuolization of the brain, spinal cord, and optic nerve) from subchronic and chronic dietary administration in mice and rats. In addition to neuropathology, rats

also exhibited neurobehavioral changes on the day of dosing in the acute neurotoxicity study. Decreased motor activity was observed in the acute neurotoxicity study as well as in offspring in the developmental neurotoxicity (DNT) study. Several rat studies also noted effects in the liver (increased organ weights and tumors) at doses similar to or above those where CNS effects were seen. The liver was identified in metabolism studies as the single organ to have the highest recovery of administered dose.

There was evidence of increased quantitative susceptibility to offspring in the database as a result of chlorfenapyr exposure. In the two-generation reproduction study, decreased pup weights were seen at a lower dose than parental toxicity (decreased body-weight). In the DNT study, offspring toxicity (decreased motor activity and increased pup deaths on postnatal days 1-4) was seen in the absence of maternal toxicity. Additional effects on the CNS (vacuolation of white matter in the brain and decreased hippocampus size) were also observed in offspring at a higher dose in this study. There was no evidence of increased susceptibility to offspring in the developmental toxicity studies. In both the rat and rabbit developmental toxicity studies, although no maternal or developmental effects were noted up to the highest doses tested (HDT), maternal observations are limited in these developmental studies. Consequently, the data from the DNT are considered more robust for assessing the effects of chlorfenapyr on the nervous system.

Given the lack of toxicity in the rat and rabbit developmental studies, the early pup deaths in the reproduction toxicity and DNT studies are suspected to be the result of postnatal exposure through lactation. Chlorfenapyr has a relatively high octanol-water partition coefficient ( $\log K_{OW} = 4.83$ ) and has been shown to accumulate in milk due to

its lipophilic nature in a dietary cow study. In addition, in a rat metabolism study, chlorfenapyr was found to accumulate in the fat, such that females exhibited greater accumulation than males. This suggests chlorfenapyr is capable of accumulating in breast milk and likely causing the early pup deaths seen in the reproduction toxicity and DNT studies through lactation.

Chlorfenapyr did not show any evidence of mutagenicity in *in vitro* or *in vivo* studies. Chlorfenapyr is classified as “suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.”

Specific information on the studies received and the nature of the adverse effects caused by chlorfenapyr as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document entitled “Chlorfenapyr: Revised Preliminary Human Health Risk Assessment for Registration Review,” dated September 7, 2016, which can be found in docket ID number EPA-HQ-OPP-2010-0467 as well in the document completed in support of this tolerance action entitled “Chlorfenapyr. Human Health Risk Assessment for the Establishment of a Tolerance without a U.S. Registration for Residues in/on Imported Tea,” dated March 1, 2017, which can be found in docket ID number EPA-HQ-OPP-2016-0333.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of

reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for chlorfenapyr used for human risk assessment is shown in Table 1 of this unit.

**Table 1 -- Summary of Toxicological Doses and Endpoints for Chlorfenapyr for Use in Human Health Risk Assessment**

<b>Exposure/Scenario</b>	<b>Point of Departure and Uncertainty/Safety Factors</b>	<b>RfD, PAD, LOC for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Acute Dietary (All populations)	NOAEL = 5 mg/kg/day UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X FQPA SF = 1X	Acute RfD = 0.05 mg/kg/day  aPAD = 0.05 mg/kg/day	Developmental Neurotoxicity Study (Rat) LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1-4) and decreased motor activity.



Chronic Dietary (All populations)	NOAEL = 5 mg/kg/day UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X FQPA SF = 1X	Chronic RfD = 0.05 mg/kg/day  cPAD = 0.05 mg/kg/day	Developmental Neurotoxicity Study (Rat) LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1-4) and decreased motor activity.  Chronic Neurotoxicity Study (Rat) NOAEL = 2.6 mg/kg/day. LOAEL = 13.6 mg/kg/day based on alterations of the myelin of the CNS and decreased water consumption in male rats, decreased food consumption in females, and decreased body-weight in both sexes.
Incidental Oral Short-Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL = 5 mg/kg/day UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X FQPA SF = 1X	Residential LOC for MOE = 100	Developmental Neurotoxicity Study (Rat) LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1-4) and decreased motor activity.
Dermal Short-Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL = 5 mg/kg/day UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X FQPA SF = 1X	Residential LOC for MOE = 100	Developmental Neurotoxicity Study (Rat) LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1-4) and decreased motor activity.
Inhalation Short-Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL = 5 mg/kg/day UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X FQPA SF = 1X	Residential LOC for MOE = 100	Developmental Neurotoxicity Study (Rat) LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1-4) and decreased motor activity.
Cancer (oral, dermal, inhalation)	Classified as “suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.” The Agency determined that quantification of risk using a non-linear approach (i.e., using a cRfD) adequately accounts for all chronic toxicity, including carcinogenicity that could result from exposure to chlorfenapyr.		

NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor.  $UF_A$  = extrapolation from animal to human (interspecies).  $UF_H$  = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to chlorfenapyr, EPA considered exposure under the petitioned-for tolerances as well as all existing chlorfenapyr tolerances in 40 CFR 180.513. EPA assessed dietary exposures from chlorfenapyr in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for chlorfenapyr. In estimating acute dietary (food only) exposure, EPA used the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID), Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003-2008. As to residue levels in food, EPA's acute analysis was unrefined and used tolerance-level residues and 100% crop-treated (PCT). Tolerances for food/feed handling establishments are not included in the acute dietary assessment unless the food/feed handling establishment is the only use; however, this is not the case for chlorfenapyr. DEEM 7.81 default processing factors were used in the

acute analysis for tomato commodities as there is a registered agricultural use on fruiting vegetables.

ii. *Chronic exposure.* In conducting the chronic dietary (food only) risk assessment, EPA used the DEEM-FCID, Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's NHANES/WWEIA from 2003-2008. As to residue levels in food, EPA's chronic dietary exposure analysis for the all population subgroups was unrefined and used tolerance-level residues and 100% PCT. As most tolerances for chlorfenapyr are for food or feed handling establishment uses and residues are expected to be incurred after processing, DEEM 7.81 processing factors were set to 1 for all commodities except tomato commodities (as there is a registered agricultural use on fruiting vegetables). For tomato commodities, default processing factors were used in the analysis.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear approach using the chronic RfD for assessing cancer risk is appropriate for chlorfenapyr; therefore, a separate quantitative cancer risk assessment is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for chlorfenapyr. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The acute and chronic dietary analysis did not include exposure from drinking water as contamination of drinking water with chlorfenapyr as a result of all registered uses, including greenhouses, is not expected to occur. Furthermore, as there are no U.S. registrations for tea, a dietary exposure assessment from drinking water is not needed.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Chlorfenapyr is currently registered for the following uses that could result in residential exposures: crack/crevice/spot treatment on indoor and outdoor residential sites (including as a bed bug treatment). Residential exposures are not expected to occur from use of chlorfenapyr on tea since chlorfenapyr will not be applied to tea in the United States. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning

the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found chlorfenapyr to share a common mechanism of toxicity with any other substances, and chlorfenapyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that chlorfenapyr does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Although there is evidence of increased quantitative susceptibility, concern is low since the offspring effects are well-characterized with clearly established NOAEL/LOAEL values and the endpoints selected for risk assessment are protective of observed offspring effects, including those observed in lactating pups.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for chlorfenapyr is complete.
- ii. Although the central nervous system is the primary target for chlorfenapyr and neurotoxic effects were observed across studies, concern is low since the selected PODs are protective of observed neurotoxic effects.
- iii. Although there is evidence of increased quantitative susceptibility, concern is low since the offspring effects are well-characterized with clearly established NOAEL/LOAEL values and the endpoints selected for risk assessment are protective of observed offspring effects.
- iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic analysis did not include exposure from drinking water as contamination of drinking water with chlorfenapyr as the result of all registered uses, including greenhouses, is not expected to occur. Furthermore, as there is no U.S. registration for tea, a dietary exposure assessment from drinking water is not needed. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by chlorfenapyr.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring

cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account the acute exposure assumptions discussed in this unit for acute exposure, the resulting acute (food only) risk estimates were less than EPA's LOC (<100% of the aPAD) for the general U.S. population (15% of the aPAD) and all population subgroups. The most highly exposed population subgroup was children 1 to 2 years old with an estimated equivalent risk to 36% of the aPAD; therefore, the acute dietary exposure to chlorfenapyr is below the Agency's LOC.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that the resulting chronic risk estimate utilizes 4.6% of the cPAD for the general U.S. population. The most highly-exposed population subgroup was children 1 to 2 years old which utilized 9.9% of the cPAD; therefore, the chronic dietary exposure to chlorfenapyr for all population subgroups is below the Agency's LOC. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of chlorfenapyr is not expected.

3. *Short- and Intermediate term risk.* Short- and intermediate-term aggregate risk assessments were performed since there is potential for post-application exposure from the previously registered uses of chlorfenapyr in residential settings. Since the short- and intermediate-term endpoints and PODs are the same, the short-term aggregate assessment is protective of intermediate-term exposure. The short-term aggregate MOE of 840 for adults is greater than the LOC (100), and is, therefore, not a concern. For children (1 to

<2 years old), the most highly exposed population subgroup, the short-term aggregate MOE of 140 is greater than the LOC (100), and is, therefore, not a concern.

4. *Aggregate cancer risk for U.S. population.* As discussed in Unit III. C.1.iii., EPA concluded that regulation based on the cRfD will be protective for both chronic and carcinogenic risks. As noted in this unit, there are no chronic risks of concern; therefore, the Agency concludes that aggregate exposure to chlorfenapyr will not pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to chlorfenapyr residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

The enforcement method is designated as M 2427, a gas chromatography/electron capture detection (GC/ECD) method with a limit of quantitation (LOQ) of 0.05 ppm. Method M 2427 has been subjected to a successful independent laboratory validation (ILV) as well as an acceptable radiovalidation using samples obtained from lettuce and tomato metabolism studies. This method is adequate for data collection and tolerance enforcement purposes.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and



Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for chlorfenapyr in or on tea, dried.

### *C. Revisions to Petitioned-For Tolerances*

EPA is establishing a tolerance for “tea, dried”, as opposed to “tea” as requested by the petitioner, for consistency with the Agency’s food and feed commodity vocabulary. In addition, EPA is amending the introductory text of paragraph (a)(1) to be consistent with the Agency’s policy for drafting the tolerance expression. These revisions reflect the language in FFDCA section 408(a)(3), which includes metabolites and degradates of a pesticide chemical under the same tolerance unless otherwise excluded, as well as providing greater clarity for measuring residues to determine compliance. These revisions do not substantively change the existing tolerances in paragraph (a)(3).

## **V. Conclusion**

Therefore, a tolerance is established without U.S. registrations for residues of chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile, in or on tea, dried at 70 parts per million.

## **VI. Statutory and Executive Order Reviews**

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled

“Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001); Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or

between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 18, 2017.

Michael Goodis,  
*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.513, revise paragraph (a)(1) to read as follows:

**§ 180.513 Chlorfenapyr; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of chlorfenapyr, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile, in or on the commodity.

Commodity	Parts per million
Tea, dried <sup>1</sup>	70
Vegetable, fruiting, group 8-10	1.0

<sup>1</sup>There are no U.S. registrations for Tea, dried as of *[insert date of publication in the Federal Register]*.

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